UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GENZYME CORPORATION Plaintiff, v. ANIKA THERAPEUTICS, INC., Defendant.	)	**C.A. NO.: _____** **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff Genzyme Corporation ("Genzyme"), by and through its undersigned counsel, files this Complaint against Anika Therapeutics, Inc. ("Anika") and alleges as follows:

The Parties

1. Plaintiff Genzyme Corporation is a corporation organized under the laws of the Commonwealth of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts.

2. Upon information and belief, Defendant Anika Therapeutics, Inc. is a corporation organized under the laws of the Commonwealth of Massachusetts, having its principal place of business at 32 Wiggins Avenue, Bedford, Massachusetts.

Jurisdiction And Venue

3. This is an action arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Anika. Upon information and belief, Anika is incorporated and maintains its principal place of business in the Commonwealth of Massachusetts. Furthermore, upon information and belief, Anika has engaged and currently engages in continuous and systematic contacts with the Commonwealth of Massachusetts.

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

The Patent-In-Suit

7. Genzyme is a global biotechnology company with products and services focused on rare inherited disorders, kidney disease, orthopedics (including the treatment of osteoarthritis), cancer, transplant and immune disease. Genzyme protects these products and services through, *inter alia*, its intellectual property portfolio, including patents. Genzyme has expended significant resources to develop and acquire this intellectual property.

8. Genzyme is an innovator and leader in the field of cross-linked hyaluronic acid technology, and in particular for its use in the treatment of knee pain in osteoarthritis of the knee.

9. Genzyme first obtained United States Food and Drug Administration ("FDA") approval of Synvisc® for the treatment of pain in osteoarthritis of the knee in the U.S. in August 1997. It was one of only two hyaluronic acid ("HA")-based treatments for the pain of osteoarthritis approved in the United States prior to 2001.

10. Synvisc® is characterized by an elastic and viscous cross-linked HA gel. The Synvisc® treatment regimen uses three injections, 7 days apart, and provides pain relief for up to 6 months.

11. Genzyme obtained FDA approval to market Synvisc-One® for the treatment of pain in osteoarthritis of the knee in February 2009. It was the first single injection HA-based treatment regimen for pain in osteoarthritis of the knee approved for sale in the U.S. Like Synvisc®, Synvisc-One® is characterized by an elastic and viscous cross-linked HA gel.

Moreover, like the Synvisc® three injection regimen, Synvisc-One®'s single injection regimen provides pain relief for up to six months.

12. Genzyme is the lawful owner of all right, title and interest in U.S. Patent 7,931,030 (the "'030 patent"), entitled "Regimens for Intra-Articular Viscosupplementation". The inventor of the '030 patent is Francois Bailleul.

13. The '030 patent claims, among other things, methods for treating a knee joint of a human subject suffering from a joint pathology, including osteoarthritis, or osteoarthritic pain in the knee joint, the method comprising a treatment regimen, the regimen being characterized by the step of administering a single administration dose, within a 24 hour period, of a viscosupplement intra-articularly into the knee joint of the human subject, wherein the viscosupplement comprises a cross-linked HA and does not contain additional active components, and wherein the treatment regimen does not comprise administering the viscosupplement in weekly intervals.

14. The United States Patent and Trademark Office ("PTO") duly and legally issued the '030 patent on April 26, 2011. A true and correct copy of the claims as allowed in the 11/313,706 application that issued as the '030 patent is attached to this Complaint as Exhibit A.[1]

Factual Background

15. Upon information and belief, Anika manufactures and sells Monovisc®, an injectable product that is used for the treatment of osteoarthritis, and in particular, osteoarthritic pain in the knee joint. Upon further information and belief, Anika manufactures Monovisc® at facilities located within the Commonwealth of Massachusetts.

[1] Note that Exhibit A shows the claims as allowed at the close of prosecution. The PTO will renumber the claims and correspond the appropriate dependent claims in the issued '030 patent.

16. Upon information and belief, Anika received European CE Mark approval for Monovisc® in October 2007, and began sales of Monovisc® in Europe during the second quarter of 2008. Upon further information and belief, Anika also began sales of Monovisc® in Turkey during the second quarter of 2008.

17. Upon information and belief, Anika received approval to market Monovisc® in Canada in August 2009, and began sales of Monovisc® in Canada during 2009.

18. Upon information and belief, Anika has applied to the FDA for approval to sell Monovisc® in the United States for the treatment of osteoarthritis, and in particular, the symptomatic relief of osteoarthritic knee pain.

19. Specifically, upon information and belief, Anika:

a. filed an investigational device exemption application with the FDA;

b. completed the clinical segment of the U.S. Monovisc® pivotal trial in June 2009;

c. completed a follow-on retreatment study in September 2009;

d. submitted the final module of a Pre-Market Approval ("PMA") filing for Monovisc® with the FDA in December 2009; and

e. has requested a review of its application by the FDA Orthopedic Advisory Panel.

20. Upon information and belief, Anika has publicly stated that it expects to receive PMA approval for Monovisc® for the treatment of osteoarthritis, and in particular, osteoarthritic knee pain, in the United States, and to launch Monovisc® in the United States.

21. Upon information and belief, Anika has publicly stated that it will commercialize Monovisc® for the treatment of osteoarthritis, and in particular, osteoarthritic knee pain, in the United States, and that it will add resources and materials to implement this plan.

22. Upon information and belief, Anika has already begun advertising for field sales representatives for Monovisc® in the United States.

23. Upon information and belief, in view of Anika's public statements and actions concerning its intent to enter the U.S. market upon FDA approval of the PMA for Monovisc®, it is unlikely that Anika will make any material alterations to Monovisc® as described in its pending PMA.

24. Upon information and belief, Monovisc® is a viscoelastic supplement composed of cross-linked sodium hyaluronate, with no other active components, that is administered in an single, intra-articular injection regimen characterized by the step of administering a single administration dose within a 24 hour period, which regimen does not comprise administration in weekly intervals.

COUNT I
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT 7,931,030 BY ANIKA)

25. Genzyme realleges and incorporates by reference paragraphs 1 through 24, inclusive, as if fully set forth in this paragraph.

26. Upon information and belief, Monovisc® is a single injection viscoelastic supplement composed of cross-linked sodium hyaluronate, with no other active components, that will be administered in a single dose within a 24 hour period, and that will not be administered in weekly intervals.

27. Upon information and belief, after receipt of regulatory approval from the FDA, Anika will make, use, sell and/or offer to sell FDA-approved Monovisc® in the United States for the treatment of osteoarthritis, and in particular, osteoarthritic pain in the knee.

28. Upon information and belief, Anika will directly infringe, contributorily infringe and/or actively induce the infringement by others under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, one or more claims of the '030 patent, by activities including but not limited to using, selling, importing and/or offering to sell FDA-approved Monovisc® in the United States for the treatment of osteoarthritis and osteoarthritis pain in the knee, together with instructing, directing, and/or advising others how to carry out such infringement using such Monovisc®.

29. Upon information and belief, Anika will sell FDA-approved Monovisc® with a package insert that will include instructions for a method of treating osteoarthritis, and in particular, osteoarthritic pain in the knee using such Monovisc®.

30. Upon information and belief, Anika will actively induce the infringement of one or more claims of the '030 patent, either literally or under the doctrine of equivalents, by offering for sale and/or selling FDA-approved Monovisc® in the United States, together with a package insert setting forth instructions for a method of treating osteoarthritis, and in particular, osteoarthritic pain in the knee using such Monovisc®.

31. Upon information and belief, when physicians or others use FDA-approved Monovisc® according to the method of treating osteoarthritis, and in particular, osteoarthritic pain in the knee set forth on the package insert provided by Anika, those acts will constitute direct infringement of one or more claims of the '030 patent, either literally or under the doctrine of equivalents.

32. Upon information and belief, Anika will contributorily infringe, either literally or under the doctrine of equivalents, one or more claims of the '030 patent by offering for sale and/or selling FDA-approved Monovisc® in the United States, while knowing that such Monovisc® is especially made or especially adapted for use in the infringement of the '030 patent, and is not a staple article suitable for substantial non-infringing use.

33. Upon information and belief, Anika knew or should have known of the '030 patent as of at least the date of Anika's first FDA filing in connection with its application for approval of Monovisc® in the United States. Anika knew or should have known of the '030 patent at this time because, among other reasons, a corporate entity that conducts diligence to protect its intellectual property would have been aware of the application for the '030 patent, the prosecution status of which was publicly available via Patent Application Information Retrieval at the PTO website (http://portal.uspto.gov/external/portal/pair) since the application published in July 2006. Upon information and belief, Anika also knew or should have known of the '030 patent as of at least March 15, 2011, when Genzyme's counsel informed Anika's counsel of the existence of the application for the '030 patent. *See* Transcript of Scheduling Conference, *Genzyme Corp. v. Anika Therapeutics, Inc.*, No. 10-cv-11146-DJC, at 5-6 (D. Mass. March 15, 2011), a true and correct copy of which is attached to this Complaint as Exhibit B. Indeed, on that date, Genzyme's counsel provided Anika's counsel with copies of the March 14, 2011 Notice of Allowance and Examiner's Amendment that included, *inter alia*, the allowed independent claims in U.S. Patent Application 11/313,706, which issued as the '030 patent. The filing of this Complaint also constitutes actual notice of the '030 patent to Anika under 35 U.S.C. § 287.

34. By virtue of, *inter alia*, the facts alleged in paragraphs 25-33, inclusive, of this Complaint, there exists an actual and justiciable case or controversy between the parties that is ripe for adjudication under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) as to whether Anika will infringe one or more claims of the '030 patent.

Prayer For Relief

WHEREFORE, Genzyme requests the Court to enter judgment in its favor and grant the following relief:

(a) A judgment that Anika will directly infringe, contribute to and/or actively induce the infringement of the '030 patent by using, selling, importing and/or offering to sell FDA-approved Monovisc® in the United States;

(b) A judgment and order permanently restraining and enjoining Anika and its directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from infringing the '030 patent by using, selling, importing or offering for sale FDA-approved Monovisc® in the United States;

(c) A judgment and order requiring Anika to pay all available and legally permissible damages to compensate Genzyme for Anika's infringing acts, but in no event less than a reasonable royalty in accordance with 35 U.S.C. § 284;

(d) A finding that the complained-of conduct by Anika has been willful, warranting an award of treble damages under 35 U.S.C. § 284;

(e) A finding that this case is exceptional under 35 U.S.C. § 285, warranting an award to Genzyme of its costs, including attorney fees and other expenses incurred in connection with this action;

(f) A judgment and order requiring Anika to pay Genzyme pre-judgment interest and post-judgment interest on all damages awarded; and

(g) Such further relief as this Court deems just and appropriate.

Demand For Jury Trial

Pursuant to Fed. R. Civ. P. 38, Genzyme demands a trial by jury of all issues so triable.

Respectfully submitted,

Dated: April 26, 2011

By: /s/ Lara Oravec

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